4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 161, 164, 184, and 186

[Docket No. FDA-2019-N-4750]

RIN 0910-AI15

Revocation of Uses of Partially Hydrogenated Oils in Foods; Confirmation of Effective

Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA or we) is confirming the effective date of December 22, 2023, for the final rule that appeared in the Federal Register of August 9, 2023. The direct final rule amends our regulations to no longer provide for the use of partially hydrogenated oils (PHOs) in food given our determination that PHOs are no longer generally recognized as safe (GRAS). The rule also revokes prior sanctions (i.e., pre-1958 authorization of certain uses) for the use of PHOs in margarine, shortening, and bread, rolls, and buns based on our conclusion that these uses of PHOs may be injurious to health. This document confirms the effective date of the direct final rule.

DATES: The effective date of December 22, 2023, for the direct final rule published in the Federal Register of August 9, 2023 (88 FR 53764) is confirmed.

FOR FURTHER INFORMATION CONTACT: Ellen Anderson, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety (HFS-225), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378 or Keronica Richardson, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of August 9, 2023 (88 FR

53764), FDA issued a direct final rule amending its regulations that provide for the use of PHOs

given our determination that PHOs are no longer GRAS and revoking prior sanctions (i.e., pre-

1958 authorization of certain uses) for the use of PHOs in margarine, shortening, and bread, rolls,

and buns based on our conclusion that these uses of PHOs may be injurious to health. The direct

final rule provided a 75-day comment period ending October 23, 2023. We stated that the

effective date of the direct final rule would be on December 22, 2023, 60 days after the end of the

comment period, unless any significant adverse comment was submitted to FDA during the

comment period. We did not receive any significant adverse comments.

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 371, 379e. Accordingly, the amendments

issued thereby are effective on December 22, 2023.

Dated: December 11, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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